

Hand-Delivered

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
CASE NO 3:22-cv- 86-MOC

UNITED STATES OF AMERICA;
STATES OF NORTH CAROLINA,
CALIFORNIA, CONNECTICUT,
FLORIDA, ILLINOIS, IOWA,
NEW MEXICO; NEW YORK,
TENNESSEE, TEXAS, and the
COMMONWEALTH OF VIRGINIA;

ex rel. Kim Edhegard, M.D.,

Plaintiffs,

v.

SKINCURE ONCOLOGY, LLC and
SENSUS HEALTHCARE, INC.,

Defendants.

FILED
CHARLOTTE, NC

MAR -4 2022

US DISTRICT COURT
WESTERN DISTRICT OF NC

QUI TAM COMPLAINT

*FILED IN CAMERA
AND UNDER SEAL*

JURY TRIAL DEMANDED

I. INTRODUCTION

This *qui tam* action alleges violations of the federal False Claims Act, 31 U.S.C. § 3729, *et seq.*, relating to false claims and statements and/or records made to Medicare and Medicaid in relation to Defendants' practices and agreements to provide kickbacks to various dermatology practices for referrals and billing of Superficial Radiation Therapy ("SRT") and related services. Defendants' practices and agreements in relation to the treatment of certain types of skin cancers with SRT

specifically violate the False Claims Act, the Anti-Kickback Statute, and the Stark Act. Relator Dr. Kim Edhegard, M.D., brings this action on his own behalf, and on behalf of the United States of America, and the States of North Carolina, California, Connecticut, Florida, Illinois, Iowa, New Mexico, New York, Tennessee, Texas, and the Commonwealth of Virginia against Defendants SkinCure Oncology LLC and Sensus Healthcare Inc.

II. JURISDICTION AND VENUE

1. This action arises under the laws of the United States of America to redress violations of the federal False Claims Act, 31 U.S.C. § 3729 *et seq.*

2. This Court's subject-matter jurisdiction is conferred by 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1331, 1345.

3. The Court has jurisdiction over Defendants' violations of the false claims act statutes of the States of North Carolina, California, Connecticut, Florida, Illinois, Iowa, New Mexico, New York, Tennessee, Texas, the Commonwealth of Virginia pursuant to 31 U.S.C. § 3732(b) because Defendants' violations of the federal False Claims Act arise from the same transactions and occurrences. The Court has pendant jurisdiction over Defendants' state law violations because these state law violations and claims, and Defendants' violations of the federal False Claims Act, arise out of a common nucleus of operative facts

4. The Court has personal jurisdiction over Defendant SkinCure Oncology, LLC because 31 U.S.C. 3732(a) authorizes nationwide service of process, and because Defendant has minimum contacts with the United States, and can be found in, transacts, or has transacted, business in the Western District of North Carolina, including through multiple locations within Mecklenburg County, North Carolina.

5. The Court has personal jurisdiction over Defendant Sensus Healthcare Inc., because 31 U.S.C. 3732(a) authorizes nationwide service of process, and because Defendant has minimum contacts with the United States, and can be found in, transacts, or has transacted, business in the Western District of North Carolina, including through multiple locations within Mecklenburg County, North Carolina.

6. Venue lies within the Western District of North Carolina under 28 U.S.C. § 1391(b),(c) and 31 U.S.C. § 3732(a) because an act proscribed by 31 U.S.C. § 3729 occurred within the district.

7. Relator Kim Edhegard, M.D. is the original source of all information upon which this Complaint is based regarding the Defendants, as that phrase is used in the federal False Claims Act, and he has provided information of the allegations of this Complaint to the United States pursuant to 31 U.S.C. § 3730(b), prior to filing this Complaint.

III. THE PARTIES

A. *RELATOR KIM EDHEGARD, M.D.*

8. Plaintiff/Relator, Kim Edhegard, M.D. is a resident of Burke County, North Carolina, and a citizen of the United States of America.

9. Dr. Edhegard is a dermatologist and is licensed to practice dermatology under the laws of the State of North Carolina.

10. Dr. Edhegard earned his medical degree from the University of South Alabama College of Medicine in 2006. He completed his internship at Brooke Army Medical Center. He completed a residency in dermatology at the University of North Carolina at Chapel Hill, followed by a fellowship in immunodermatology at Duke University.

11. Dr. Edhegard is board certified by the American Board of Dermatology.

B. *DEFENDANT SKINCURE ONCOLOGY, LLC.*

12. Defendant SkinCure Oncology, LLC (hereafter “SkinCure”) is organized under the laws of Delaware and upon information and belief is a subsidiary of defendant Sensus Healthcare, Inc. (hereafter “Sensus”).

13. SkinCure is a national company aligned with Sensus Healthcare to develop “management relationships” with dermatology practices.

14. As part of its management relationship with Sensus, SkinCure is providing and billing for SRT treatments and related services through multiple locations within Mecklenburg County, North Carolina

C. DEFENDANT SENSUS HEALTHCARE, INC.

15. Sensus Healthcare Inc. is a publicly traded medical device company based in Boca Raton, Florida. Sensus is listed on NASDAQ as SRTS; SRTSW.

16. According to its website, Sensus is committed to enabling non-invasive and cost-effective treatment of non-melanoma skin cancers and keloids. Sensus uses a proprietary low energy x-ray radiation technology known as superficial radiation therapy (“SRT”).

17. Sensus has incorporated SRT into its portfolio of treatment devices, including the SRT-100 and SRT-100 Vision.

18. According to Sensus’ website, SRT is used by at least 160 dermatology practices nationwide and has been used to treat more than 30,000 people.

19. Through its management relationship with SkinCure, Sensus is providing and billing for SRT treatments and related services through at least four locations within Mecklenburg County, North Carolina.

IV. MEDICARE

20. In 1965, Congress enacted Title XVII of the Social Security Act, which established the Medicare Program to provide health insurance for the elderly and disabled. Medicare is a health insurance program for people age 65 or older and for people under age 65 with certain disabilities. Medicare now has four parts: Part A (Hospital Insurance); Part B (Medical Insurance), Part C (Managed Care Plans), and Part D (Prescription Drug Program).

21. Reimbursement for medical services and supplies for dermatology services are covered under Medicare Part B. 42 U.S.C. §§ 1395j–1395w-5.

22. Subject to state regulations, medical service vendors seeking reimbursement must use claim forms and standardized coding of medical services under state law.

23. Under Medicare Part B, a physician may take an assignment of coverage from a qualified patient to obtain reimbursement under Medicare, in which case the provider becomes a “participating provider.” 42 U.S.C. 1395u(h)(1); 42 U.S.C. § 1395u(i); 42 C.F.R. § 414.20.

24. When a physician becomes a participating provider, the physician is required to follow billing, accounting, and documentation requirements imposed by regulations and the Medicare Administrative Contractor (“MAC”). 42 U.S.C. § 1320c-5(a); 42 C.F.R. § 424.5. MACs are typically insurance companies and perform all of the duties previously performed by fiscal intermediaries.

V. MEDICAID

25. Under the Medicaid provisions of the Social Security Act, States may create state health care benefit programs and obtain federal financial support for those programs. 42 U.S.C. §§ 1396–1396w-5; *see also* 42 C.F.R. § 430.10.

26. The United States and each State jointly contribute to the Medicaid program. The proportion of the state-federal split varies from state to state, but the federal government provides at least half of each state's Medicaid budget.

27. Federal participation is largely limited to the provision of matching funds and enforcement of minimum administrative standards. Appropriations are made from the United States Treasury to support the Medicaid program. 42 U.S.C. § 1396; *see also* 42 C.F.R. Parts 430, 431, 433.

28. The medical assistance available under Medicaid is defined by 42 U.S.C. § 1396d; *see also* 42 C.F.R. § 433.56. Subject to state regulations, medical service vendors seeking reimbursement must use claim forms and standardized coding of medical services under state law.

29. As with Medicare, MACs also assist in the administration of each state's Medicaid program. Each state's program varies slightly, but each requires compliance with terms very similar to those of Medicare, as outlined above.

30. The prohibition against physician self-referrals applies to the Medicaid program. 42 U.S.C. § 1396b(s) (effective Jan. 1, 1995).

VI. OTHER GOVERNMENT PAYORS

31. In addition to Medicare and Medicaid, the United States also pays for programs such as Federal Employees Health Benefits Program (FEHB) (which covers federal employees) and Tricare (which covers members of the military and their families).

32. Each State also offers a variety of plans for its employees, including state-wide plans for teachers, firefighters, and police officers. These programs are largely subject to the same rules, regulations and standards set forth above in the context of Medicare.

VII. THE FEDERAL FALSE CLAIMS ACT

33. The Federal False Claims Act creates civil liability for any person who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” and provides:

(a) Any person who (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (3) conspires to commit a violation of (1) or (2) is liable to the United States Government for a civil penalty of not less than \$5,500 and not more than \$11,000, plus three times the amount of damages which the Government sustains because of the act of that person. 31 U.S.C. § 3729(a)(1)(A), (B) and (C).

(b) For purposes of this section, the terms “knowing” and “knowingly” mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity

of the information, and no proof of specific intent to defraud is required.
31 U.S.C. § 3729(b)(1).

31 U.S.C. § 3729(a)(1)(A), (B) and (C).

34. Claims for reimbursement from government payors arising from violations of the Stark Act, 42 U.S.C. § 1395nn, and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7(b)), *infra*, are violations of the False Claims Act because the violations cause claims to be made for or to ineligible recipients.

VIII. THE STARK ACT

35. The Stark Act prohibits claims for designated health services when referred by physicians with financial interests in the provisions of those services and/or when there is compensation to a physician or group practice directly or indirectly tied to the “volume or value of any referrals.” 42 U.S.C. § 1395nn.

IX. THE ANTI-KICKBACK STATUTE

36. The Anti-Kickback Statute creates civil and criminal liability for anyone to “knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward the referral of business reimbursable under any of the Federal health care programs....” 42 U.S.C. § 1320a-7b(f).

37. Under the Anti-Kickback Statute, a federal health care program is: “(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United

States Government (other than the health insurance program under chapter 89 of title 5); or (2) any State health care program, as defined in section 1320a-7(h) of this title.” 42 U.S.C. § 1320a-7(b)(f).

38. Kickbacks are harmful because they can distort medical decision-making, cause overutilization, increase costs to the federal health care programs, and result in unfair competition by freezing out competitors unwilling to pay kickbacks.

39. Both parties to an impermissible kickback transaction may be liable.

40. In addition, health care claims procured as a result of a kickback are ineligible for payment by government health programs; the presentation of a claim for services procured by a kickback are therefore false.

X. DEFENDANTS’ PROGRAM SERVICE AGREEMENT VIOLATES THE STARK ACT AND THE ANTI-KICKBACK STATUTE

41. Dr. Edhegard opened Foothills Family Dermatology, LLC in Morganton, North Carolina in 2021.

42. Defendants approached Dr. Edhegard and offered to enter into a Program Service Agreement with him.

43. Defendants’ Program Service Agreement would explicitly give Dr. Edhegard percentage-based and referral-driven compensation in exchange for his referrals to Defendants’ equipment, employees, radiation therapy, and radiation treatment delivery services, including SRT.

44. Defendants' Program Service Agreement proposed that income from the performance of SRT treatments would be split between Dr. Edhegard and Defendants, with 60% going to Defendants as a management fee and 40% going to Dr. Edhegard.

45. Defendants' Program Service Agreement further proposed that if the average daily census exceeded fifteen patients for three consecutive months, the management fee would be reduced from 60% to 55%, which would operate to increase Dr. Edhegard's percentage from 40% to 45%.

46. If the average daily patient census exceeded 20 patients per day, then the management fee would be further reduced to 50%, which would automatically increase Dr. Edhegard's percentage to 50%.

47. Defendants' Program Service Agreement further proposed that Defendant SkinCure would pay all costs and expenses associated with installing the necessary SRT equipment in Dr. Edhegard's office, and further that Defendant SkinCure would pay the salary of the employee performing the SRT treatments.

48. Sensus salesman David Westerfer told the Relator that Defendants use this exact same Program Service Agreement to develop referral-driven compensation schemes and agreements with dermatologist across the United States, including within the States of North Carolina, California, Connecticut, Florida, Illinois, Iowa, New Mexico, New York, Tennessee, Texas, and the Commonwealth of Virginia.

49. Defendants' proposed Program Service Agreement expressly compensates participating doctors, such as Dr. Edhegard, based upon the number of referrals made for SRT treatments.

50. Defendants' conduct violates the Stark Act because participating physicians and dermatologists have a financial interest in the SRT treatments for which they are making referrals, and their compensation pursuant to the Program Service Agreement is tied to the volume of their referrals.

51. Defendants' conduct violates the Anti-Kickback Statute because participating physicians and dermatologist have a financial interest in the SRT treatments for which they are making referrals, and their compensation pursuant to the Program Service Agreement is tied to the volume of their referrals.

52. Each of the Defendants' arrangements, with more than 160 practices around the United States, violates both the Stark Act and the Anti-Kickback Statute.

53. Because the United States does not pay claims tainted by kickbacks, every claim for SRT services submitted by one of these 160 providers across the country were ineligible for payment.

54. Because the claims were ineligible for payment, they were thus false.

COUNT I
VIOLATION OF THE FEDERAL FALSE CLAIMS ACT
31 U.S.C. § 3729(a)(1)(A)

55. The Relator re-alleges paragraphs 1 – 54 as fully set forth herein.

56. Through the acts described above, Defendants SkinCure and Sensus knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the United States under the Medicare and Medicaid Programs in violation of 31 U.S.C. § 3729(a)(1)(A).

57. Because of the presentation of false or fraudulent claims, the United States has reimbursed Defendants for services that it otherwise would not have.

58. By reason of the Defendants' unlawful acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

59. All of the Defendants' conduct described in this Complaint was knowing, as that term is used in the federal False Claims Act.

COUNT II
VIOLATION OF THE FEDERAL FALSE CLAIMS ACT
31 U.S.C. § 3729(a)(1)(B)

60. The Relator re-alleges paragraphs 1 – 59 as fully set forth herein.

61. Defendants knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims paid or approved by the United States under the Medicare and Medicaid Programs in violation of 31 U.S.C. § 3729(a)(1)(B).

62. Defendants made or caused to be made such false records and statements to Medicare and Medicaid, which were material to their false or fraudulent claims, because the arrangements Defendants have with medical providers caused the medical providers to administer treatment to patients, including SRT, in violation of the Stark Act and the Ant-Kickback Statute.

63. Because of Defendants' use of false records or statements, the United States reimbursed the Defendant for services that it otherwise would not have.

64. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

65. All of the Defendants' conduct described in this Complaint was knowing, as that term is used in the federal False Claims Act.

COUNT III
NORTH CAROLINA FALSE CLAIMS ACT
N.C. Gen. Stat. § 1-607(a)(1) and (2)

66. The Relator re-alleges paragraphs 1 – 65 as fully set forth herein.

67. At all relevant times the Defendants transacted business in the State of North Carolina, including committing the violations alleged in this Complaint.

68. The above allegations violate the North Carolina False Claims Act.

69. As a result of these violations, the State of North Carolina has been damaged in an amount to be proven at trial.

COUNT IV
TEXAS WHISTLEBLOWER LAW
Tex. Gov't Code §§ 554.001 *et seq.*
TEXAS MEDICAID FRAUD PREVENTION ACT
Tex. Hum. Res. Code § 36 *et seq.*

70. The Relator re-alleges paragraphs 1 – 65 as fully set forth herein.

71. At all relevant times the Defendants transacted business in the State of Texas, including committing the violations alleged in this Complaint.

70. The above allegations violate the Texas Whistleblower Act and Texas Medicaid Fraud Prevention Act.

73. As a result of these violations, the State of Texas has been damaged in an amount to be proven at trial.

COUNT V
CALIFORNIA FALSE CLAIMS ACT
Cal. Gov't Code § 12650 *et. seq.*

74. The Relator re-alleges paragraphs 1 – 65 as fully set forth herein.

75. At all relevant times the Defendants transacted business in the State of California, including committing the violations alleged in this Complaint.

76. The above allegations violate the California False Claims Act.

77. As a result of these violations, the State of California has been damaged in an amount to be proven at trial.

COUNT VI
FLORIDA FALSE CLAIMS ACT
Fla. Stat. § 68.081 *et. seq.*

78. The Relator re-alleges paragraphs 1 – 65 as fully set forth herein.

79. At all relevant times the Defendants transacted business in the State of Florida, including committing the violations alleged in this Complaint.

80. The above allegations violate the Florida False Claims Act.

81. As a result of these violations, the State of Florida has been damaged in an amount to be proven at trial.

COUNT VII
ILLINOIS FALSE CLAIMS ACT
740 Ill. Comp. Stat. 175/1. *et seq.*

82. The Relator re-alleges paragraphs 1 – 65 as fully set forth herein.

83. At all relevant times the Defendants transacted business in the State of Illinois, including committing the violations alleged in this Complaint.

84. The above allegations violate the Illinois False Claims Act.

85. As a result of these violations, the State of Illinois has been damaged in an amount to be proven at trial.

COUNT VIII
IOWA FALSE CLAIMS ACT
Iowa Code § 685.1 *et seq.*

86. The Relator re-alleges paragraphs 1 – 65 as fully set forth herein.

87. At all relevant times the Defendants transacted business in the State of Iowa, including committing the violations alleged in this Complaint.

88. The above allegations violate the Iowa False Claims Act.

89. As a result of these violations, the State of Iowa has been damaged in an amount to be proven at trial.

COUNT IX
NEW YORK FALSE CLAIMS ACT
N.Y. State Fin. Law § 187 *et seq.*

90. The Relator re-alleges paragraphs 1 – 65 as fully set forth herein.

91. At all relevant times the Defendants transacted business in the State of New York, including committing the violations alleged in this Complaint.

92. The above allegations violate the New York False Claims Act.

93. As a result of these violations, the State of New York has been damaged in an amount to be proven at trial.

COUNT X
CONNECTICUT FALSE CLAIMS ACT
Conn. Gen. Stat. § 4-274 *et seq.*

94. The Relator re-alleges paragraphs 1 – 65 as fully set forth herein.

95. At all relevant times the Defendants transacted business in the State of Connecticut, including committing the violations alleged in this Complaint.

96. The above allegations violate the Connecticut False Claims Act.

97. As a result of these violations, the State of Connecticut has been damaged in an amount to be proven at trial.

COUNT XI
TENNESSEE FALSE CLAIMS ACT
Tenn. Code Ann. § 4-18-101 *et seq.*

98. The Relator re-alleges paragraphs 1 – 65 as fully set forth herein.

99. At all relevant times the Defendants transacted business in the State of Tennessee, including committing the violations alleged in this Complaint.

100. The above allegations violate the Tennessee False Claims Act.

101. As a result of these violations, the State of Tennessee has been damaged in an amount to be proven at trial.

COUNT XII
NEW MEXICO MEDICAID FALSE CLAIMS ACT
N.M. Stat. Ann. § 27-14-1 *et seq.*
NEW MEXICO FRAUD AGAINST TAXPAYERS ACT
N.M. Stat. Ann. § 44-9-1 *et seq.*

102. The Relator re-alleges paragraphs 1 – 65 as fully set forth herein.

103. At all relevant times the Defendants transacted business in the State of New Mexico, including committing the violations alleged in this Complaint.

104. The above allegations violate the New Mexico Medicaid False Claims Act and the New Mexico Fraud Against Taxpayers Act.

105. As a result of these violations, the State of New Mexico has been damaged in an amount to be proven at trial.

COUNT XIII
VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. § 8.01-216.1 *et seq.*

106. The Relator re-alleges paragraphs 1 – 65 as fully set forth herein.

107. At all relevant times the Defendants transacted business in the State of Virginia, including committing the violations alleged in this Complaint.

108. The above allegations violate the Virginia Fraud Against Taxpayers Act.

109. As a result of these violations, the Commonwealth of Virginia has been damaged in an amount to be proven at trial.

WHEREFORE, Relator Dr. Edhegard, requests the following relief:

- A. Judgment against Defendants for three times the amount of damages the United States has sustained because of their actions, plus a civil penalty of between \$11,803 and \$23,607 for each violation of the federal False Claims Act;
- B. that 25% of the damages and penalties obtained as a result of this action if the United States elects to intervene, and 30% if they do not, together with the maximum percentage from the False Claims Act statutes of each state;

C. that Dr. Edhegard's attorneys' fees, litigation and investigation costs, and expenses be paid by Defendants; and

D. for such other relief as the Court deems just and appropriate.

DEMAND FOR A JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the Plaintiff/Relator hereby demands a trial by jury.

Filed, this the 4th day of March, 2022

/s/ Mark A. Jones

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